MAR - 7 2014

510(K) SUMMARY: IMPAX Volume Viewing

Common/Classification Name: Picture Archiving and Communications System 21CFR 892.2050
Proprietary Name: IMPAX Volume Viewing
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Koen Cobbaert, Prepared: July 24, 2013
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's IMPAX Volume Viewing, which is a picture archiving and communications system. It is substantially equivalent to Agfa's IMPAX Volume Viewing 2.0 (K111638), Agfa's Registration and Fusion (K080013), Agfa's Web1000 (K053458) and Voxar's 3D Enterprise with ColonMetrix and PET/CT Perfusion (K070831).

B. DEVICE DESCRIPTION

The new device is similar to the predicate devices. All are PACS system accessories that allow the user to view and manipulate 3D image data sets. This new version includes automated removal of bone-like structures, stenosis measurement and web-browser access.

Principles of operation and technological characteristics of the new and predicate devices are the same.

C. INTENDED USE

IMPAX Volume Viewing software is a visualization package for PACS workstations. It is intended to support radiographer, medical imaging technician, radiologist and referring physician in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. The software is intended as a general purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features.

Other optional functionality is intended for the registration of anatomical (CT) on functional volumetric image data (MR) to facilitate the comparison of various lesions. Volume and distance measurements are intended for evaluation and quantification of tumor measurements, and other analysis and evaluation of both hard and soft tissues. The software also supports interactive segmentation of a region of interest (ROI).

Web-browser access is available for review purposes. It should not be used to arrive at a diagnosis, treatment plan, or other decision that may affect patient care.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's IMPAX Volume Viewing has an Indications for Use statement largely similar to the statements for the predicate devices (K111638, K053458, K022292, K080013 and K070831). Intended uses are the same. As software accessories to PACS systems, the predicate and new devices have the same technological characteristics. Software is used to identify characteristic patterns within 3D image data which the user can then view and manipulate. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

Product Comparison Table – Volume Viewing			
	IMPAX Volume Viewing NEW DEVICE	IMPAX with MPR, Digital Subtraction and 3D, Volume Viewing and Web1000 PREDICATES K022292/K111638/K053458 /K080013	Voxar 3D Enterprise with ColonMetrix and PET/CT Perfusion PREDICATE K070831
3D Volume rendering	X	X	X
MPR, CPR	X	X	X
MIP, MinIP, AvgIP	X	X	X
Fusion and subtraction views	X	X	-
Can load and register two data sets for comparison (landmark based, automatic, manual)	X	X	-
Multi-modality (CT and MR) image registration	X	X	-
Anaglyphic stereo 3D Viewing	X	-	-
Segmentation tools	X	X	X
Automatic removal of the CT-table	X	X	X
Automated removal of bone-like structures	X	-	X
Volume measurements	X	X	X
Volume measurements via semi-automatic region growing	X	X	X

Product Comparison Table – Volume Viewing			
	IMPAX Volume Viewing NEW DEVICE	**IMPAX with MPR, Digital Subtraction and 3D, Volume Viewing and Web1000 PREDICATES K022292/K111638/K053458 /K080013**	**Voxar 3D Enterprise with ColonMetrix and PET/CT Perfusion PREDICATE K070831**
Vessel analysis	X	X	X
Stenosis measurements	X	-	X
DICOM and AVI movie generation	X	X	X
Reformat to a new dataset	X	X	X
Color maps & Annotations	X	X	X
Intra- or internet access for review purposes	X	X	-
User interface	IMPAX	IMPAX	Voxar

Table 1: Device Predicate Comparison

E. TECHNOLOGICAL CHARACTERISTICS

IMPAX Volume Viewing 3.0 is an accessory to Agfa's IMPAX PACS systems. It is a general purpose medical image processing tool for the reading and analysis of 3D image datasets. It is the successor to Agfa's Volume Viewing 2.0 (K111638) and adds the following new functionality: it allows the user to automatically remove bone-like structures to facilitate viewing of soft tissue such as vessels; it allows the user to measure vessel stenosis and to access medical datasets for review purposes through a web-browser.

It is a tool for conveniently viewing and manipulating cross-sectional image series' for display in any orientation and slice thickness. A second series can be registered or fused to the first automatically, manually or with user defined landmarks. Segmentation of blood vessels and air-filled structures facilitate the visualization of vessel features. Color maps, subtraction views, multiple screen layouts and tools for measurement, calculations and annotations are provided.

Volume measurement features are present in the previously cleared IMPAX Volume Viewing 2.0. To the range of available volume measurement methods Agfa added semi-automatic region growing. This feature was ported from Agfa's Registration and Fusion application (K080013).

Anaglyphic images are used to provide a stereoscopic 3D effect, when viewed with glasses where the two lenses are different (usually chromatically opposite) colors, such as red and cyan. Images are made up of two color layers, superimposed, but offset with respect to each other to produce a depth effect. The stereoscopic 3D view is available next to the "regular" 3D view. A user can toggle the image from the regular 3D view to stereo 3D. Tests by medical professionals showed that there are no specific medical or clinical benefits to using the stereoscopic 3D view. It is perceived as useful to train medical students, but has no new clinical benefits in comparison to the "regular" 3D view.

F. TESTING

Verification and validation testing confirm the device meets performance, measurement and usability requirements. No clinical trials were performed in the development of the device.

The device has been designed and manufactured to conform to the following standards:

- EN 12435:2006 Health Informatics – Expression of Results of Measurements in Health Sciences
- ISO 14971:2007 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

Verification tests for IMPAX Clinical Applications 3.0 and the web-browser component XERO Clinical Applications 1.0 covered all requirements and identified risk control measures. Software verification activities are discussed in the following documents:

- Verfication Plan IMPAX Clinical Applications 3.0
- Final Verification Report IMPAX Clinical Applications 3.0
- Verification Plan XERO Clinical Applications 1.0
- Final Verification Report XERO Clinical Applications 1.0

For this release regression testing assured the different measurement algorithms still provide the same output as the predicates Volume Viewing 2.0 (K111638) and Registration and Fusion (K080013). Testers made identical measurements of diameters, areas and volumes and compared those against reference values. Results met the established acceptance criteria of +/- scanner resolution (for dataset uncertainty).

> The filing of the Volume Viewing 2.0 predicate release (K111638) included measurement accuracy tests comparing vessel diameter and area measurements made against that of the predicate Voxar 3D Enterprise.
>
> The filing of the Registration and Fusion predicate release (K080013) included measurement accuracy tests comparing volumes selected by the semi-automatic region growing against the equivalent to Mirage 5.5 (K043441) manufactured by Segami Corporation.

The tests also included crosshair position tests to verify whether viewports link to the same location in every dataset. Results met the established acceptance criteria of half a voxel (for rounding differences across graphic video cards). The measurement plan and results are included in the report: Measurement Accuracy & Crosshair Positioning Test Plan IMPAX Clinical Applications 3.0, **Exhibit 5**.

Validation

Concept tests involving 6 medical professionals of 4 different hospitals in Belgium and the Netherlands were asked to score stereoscopic 3D viewing in comparison to "regular" 3D viewing on an earlier version of the product. The tests concluded that both viewing methods are equivalent, but that other than a useful tool to train medical students there is no distinct medical or clinical benefit to using the stereoscopic 3D view over the "regular" 3D viewing.

The application was validated in test labs and hospitals in the United Kingdom, the United States, Ireland and Belgium. 29 medical professionals participated in the validation using 154 anonymized clinical studies. No patient treatment was provided.

Objectives of the validation were to evaluate:

- If the centerline computation in contrast-filled vessels can be adequately traced and if vessels can be adequately visualized in CT angiography vessel tracking. (Done via a side-by-side comparison with the IMPAX Volume Viewing 2.2 predicate). If the user can determine the amount of stenosis in an artery (Done via a side-by-side comparison with the Voxar 3D predicate)
- If bone-like structures in CT angiography datasets of the thorax, abdomen, pelvis and upper/lower extremities are adequately removed from view[2] (done via a side-by-side comparison with the Voxar predicate).
- If the user can perform volume measurements through manual slice-by-slice contouring or through (semi-) automated segmentation in a user friendly and intuitive way .
- If the Image quality of the 2D and 3D image rendering algorithms is adequate (Done via a side-by-side comparison with the IMPAX Volume Viewing 2.2 predicate)

A scoring scale was implemented and acceptance criteria established. Results met acceptance criteria.

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[2] Head and neck cases are not included because the vessels are often anatomically fused to the bone tissue. Vascular and osseous tissue can then not be reliably separated.

Validation activities are described in the following **Exhibit 5** documents:

- Design Validation Plan IMPAX Clinical Applications 3.0
- Design Validation Score Sheet – Vessel analysis – IMPAX Clinical Applications 3.0
- Design Validation Score Sheet – Bone Removal – IMPAX Clinical Applications 3.0
- Design Validation Score Sheet – Volume Measurements – IMPAX Clinical Applications 3.0
- Design Validation Score Sheet – Image Quality – IMPAX Clinical Applications 3.0
- Design Validation Report IMPAX Clinical Applications 3.0

The web browser component was validated by 11 medical professionals using 42 anonymized clinical data sets. The examiners focused on the usability of features and functionalities for the purpose of non-diagnostic review of CT and MR data sets using 3D and multi planar reconstructions. The design validation activities are discussed in:

- Design Validation Plan XERO Clinical Applications 1.0[3]
- Design Validation Report XERO Clinical Applications 1.0

No clinical testing was performed in the development of the new device.

All verification and validation testing has been successfully completed. Results have been reviewed by management and summarized in the report of the Final Design Review – IMPAX Clinical Applications 3.0 and XERO Clinical Applications 1.0, also included in **Exhibit 5**. Overall results are documented in **Section 5 of the Final Design Review**.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

[3] The validation plan also describes the test protocol of SPECT/CT and SPECT/MRI image registration and fusion. This functionality is part of IMPAX PET & SPECT Viewing. Agfa is not seeking US market clearance for IMPAX PET & SPECT Viewing. IMPAX PET-SPECT Viewing 3.0 contains no new functionality versus the cleared Registration and Fusion 1.0 (K080013). It retains the functionality of version 1.0.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

Agfa HealthCare N.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K133135
Trade/Device Name: IMPAX Volume Viewing 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 13, 2014
Received: February 14, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133135

Device Name
IMPAX Volume Viewing

Indications for Use *(Describe)*
IMPAX Volume Viewing software is a visualization package for PACS workstations. It is intended to support radiographer, medical imaging technician, radiologist and referring physician in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. The software is intended as a general purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features.

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Web-browser access is available for review purposes. Images accessed through a web-browser (via a mobile device or by other means) should not be used to create a diagnosis, treatment plan, or other decision that may affect patient care.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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